

REMARKS

The present application contains claims 1-85, the status of which is as follows:

- (a) Claims 5-6, 8, 12, 14, 34-35, 39, and 44 were previously presented.
- (b) Claims 49-50 and 52-53 have been currently amended.
- (c) Claims 1-4, 7, 9-11, 13, 15-33, 36-38, 40-43, 45-48, 51, and 54-85 were

previously cancelled without prejudice.

No new matter has been added.

Claim rejections under 35 U.S.C. §112

Claims 34-35, 39, and 44 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Applicants respectfully traverse these rejections.

The specification as filed clearly indicates that defibrillation apparatus 18 identifies and treats ventricular fibrillation, as indicated *inter alia* in the following passages (emphasis added):

In some preferred embodiments of the present invention, at least some of the electrodes are placed at multiple sites on the epicardium and/or endocardium of the left and right ventricles. (p. 3, lines 12-14)

Fig. 11 schematically illustrates an electrical signal applied to a beating pig heart, in accordance with a preferred embodiment of the present invention, and experimental results obtained thereby. In this experiment, a 15 Hz, 700 millisecond, 0.5 mA peak-to-peak square wave was applied in three consecutive bursts, separated by 300 milliseconds. The first burst induced an arrhythmia which looked like ventricular fibrillation, and captured the heart. Termination of the three bursts released the heart, whereupon the arrhythmia resolved, and normal cardiac activity resumed within approximately 500 milliseconds. It is believed that application of such signals to a heart already in fibrillation will similarly resolve the fibrillation within several seconds. (p. 15, lines 23-31)

By contrast to the 5 - 15 joule shocks applied during a 10 millisecond period according to conventional defibrillation techniques, the defibrillation signal utilized in this experiment delivered, per electrode, less than 10 millijoules to the heart during a period greater than 100 times as long. Because the peak rate of energy transfer to the heart during

defibrillation, as provided by these embodiments of the present invention, is approximately two to five orders of magnitude smaller than that utilized in the prior art, it is believed that shockless defibrillation provided by these embodiments is substantially safer and less traumatic than prior art defibrillation techniques. It is noted that prior art defibrillation techniques are unable to safely and effectively terminate ventricular fibrillation using shocks of significantly less than 5 - 15 joules. These techniques usually apply the energy over a period of less than 10 milliseconds. Thus, the peak rate of energy transfer to the heart associated with these techniques is typically above 500 W. Preferred embodiments of the present invention generally apply energy to the heart at a peak rate of less than about 100 W, and, as in the experiment shown in Fig. 11, can be successfully implemented using energy transfer rates significantly lower than 10 W (e.g., 10 - 100 mW).
(p. 16, lines 1-15)

Claims 34-35, 39, and 44 recite particular combinations of features of defibrillation apparatus 18. Applicants thus respectfully submit that these claim are fully supported in the specification as filed, and are thus allowable under 35 U.S.C. §112, first paragraph.

Claim rejections under 35 U.S.C. §102 and §103

Claims 5-6, 14, 34, 39, 44, and 49 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,554,922 to Prystowsky et al. Claims 12 and 53 were rejected under 35 U.S.C. §103(a) as being unpatentable over Prystowsky. Claim 50 was rejected under 35 U.S.C. §103(a) as being unpatentable over Prystowsky in view of U.S. Patent No. 5,713,924 to Min et al.

Applicants respectfully traverse these rejections. Prystowsky neither teaches nor suggests defibrillating the heart, i.e., applying his signal to a heart already in fibrillation in order to resolve the already-existing state of fibrillation. Prystowsky thus fails to teach or suggest the step of determining of fibrillation, as recited in claims 5-6, 14, 34, 39, 44, and 49.

The Examiner argued that col. 1, lines 5-8, of Prystowsky teach determining fibrillation. This passage reads in full: "The invention relates to pacemakers, and more particularly to a method of inhibiting a variety of cardiac arrhythmias, including atrial and ventricular tachycardia and fibrillation."

Applicants respectfully submit that this passage, and indeed Prystowsky as a whole, fails to teach determining a fibrillation state or defibrillating a heart already in fibrillation. The word "inhibiting" in the cited passage means "preventing," rather than terminating fibrillation after it has occurred. Prystowsky explicitly provides this definition: "It is thus an object of the present invention to inhibit arrhythmias and prevent their occurrence as opposed to treating the arrhythmias after their occurrence" (col. 2, lines 12-14; emphasis added).

Furthermore, Prystowsky distinguishes his invention over the prior art by pointing out that prior art electrical stimulation techniques are directed toward defibrillation, rather than inhibiting, i.e., preventing, fibrillation before it occurs: "Heretofore, efforts have been directed toward the treatment of arrhythmias, including fibrillation, after they occur" (col. 1, lines 17-19; emphasis added). Prystowsky also argues that prior art efforts to inhibit, i.e., prevent, fibrillation did not include electrical stimulation: "Heretofore, efforts to inhibit arrhythmias before they occur have been limited to the use of drugs. No efforts have been made to inhibit the arrhythmias using stimulators or other devices" (col. 1, lines 24-27; emphasis added).

Applicants draw the Examiner's attention to the passage at col. 5, lines 24-32, of Prystowsky, which reads in full:

Furthermore, if arrhythmic response 40 is the trigger that starts the tachycardia or fibrillation, S_c can be used to either prevent the trigger, as described above, or instead of delivering S_c after each beat 30, the spontaneous electrical activity of the heart can be sensed and whenever response 40 occurs and is sensed, S_c can be delivered in the refractory period of response 40 to prevent the subsequent tachycardia or fibrillation precipitated by the trigger 40.

The second technique described in this passage includes detecting a trigger 40 "that starts the tachycardia or fibrillation," and applying the signal S_c to "prevent the subsequent tachycardia or fibrillation precipitated by the trigger 40" (emphasis added). It is thus again clear that trigger 40 is not the tachycardia or fibrillation itself, but rather a potential precursor to tachycardia or fibrillation. As stated, the goal of applying the signal S_c is to "prevent" such "subsequent" tachycardia or fibrillation before it occurs, rather than to resolve such tachycardia or fibrillation after it has already occurred.

Applicants thus submit that claims 5-6, 14, 34, 39, 44, and 49 are in condition for allowance.

Claim rejections under 35 U.S.C. §103

Claims 8, 35, and 52 were rejected under 35 U.S.C. §103(a) as being unpatentable over Prystowsky in view of U.S. Patent Publication No. 2002/0123771 to Ideker et al. Applicants respectfully traverse these rejections. The Ideker application was filed on December 21, 2000, which is after the May 25, 2000 filing date of International Application No. PCT/IL00/00302, of which the present application is the U.S. national stage. Ideker is thus not available as prior art under 35 U.S.C. §102(e)/§103(a). Applicants also respectfully submit that Prystowsky does not teach defibrillation, as discussed above. Claims 8, 35, and 52 are thus in condition for allowance.

Amendments to the claims

Claims 49-50 and 52-53 have been amended to add that the control unit determines that fibrillation is occurring. This amendment finds support throughout the specification as filed, including near the beginning of the Summary of the Invention: "When it is determined that fibrillation or other dangerous arrhythmic activity is occurring in the heart, the control unit administers a signal. . ." (p. 2, lines 6-8).

Applicants believe the remarks presented hereinabove to be fully responsive to all of the grounds of rejection raised by the Examiner. In view of these remarks, Applicants respectfully submit that all of the claims in the present application and the specification are in order for allowance. Notice to this effect is respectfully requested.

Respectfully submitted,
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